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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,230	06/11/2001	Judith Franks-Farah	0110430-26	3728

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EXAMINER

WEBB, JAMISUE A

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 04/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/879,230

Applicant(s)

FRANKS-FARAH ET AL.

Examiner

Jamisue A. Webb

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-19 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9-14 and 20 is/are rejected.
- 7) ☒ Claim(s) 5, 7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Drawings*

1. The drawing submitted in the case are considered informal and are acceptable for examination purposes. Formal drawings must be submitted.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-4, 6, 10-14, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Karram et al. (6,238,383).

4. With respect to Claims 1, 2, 3, 6, and 10-14: Karram discloses the use of a female catheter system that includes a set of patient use catheters, with lubricant, cleansing detergent and instructions (column 7, lines 65-67). Karram discloses the use of instructions with printed matter, and even though the printed matter for claimed invention may be different from the Karram reference, any differences relate to the information or instructions conveyed by the printed matter and not in any structure of the product. The product is known in the art, and a new intended use for the product does not constitute patentable subject matter. *In re Schreiber*, 128 F. 3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997). The following is considered printed matter:

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self care documentation, acknowledgement section, step-by-step instructions, recording device, information device, contents map.

5. With respect to Claim 4: The claim does not set forth what quantity is associated with "one month of catheterizations", Karram discloses a set of catheters (column 7, lines 65-67), which the examiner considers to be sufficient for a month supply.

6. With respect to Claim 20: See Karram, Column 8, line 60 to Column 9, line 23.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4, 6, 9-14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over House (6,090,075).

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10. With respect to Claims 1-3, 6, and 9-14: House discloses the use of urinary catheters kits with antiseptic swabs, gloves and a specimen/measuring container. House however fails to disclose the use of instructions or printed documentation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have printed instructions or documentation with the kit, due to the fact that the examiner takes official notice that it is well known in any art that kits come with instructions (as can be seen by Kurram, above). Even though the printed matter for the claimed invention may be different from any instructions that are obvious over House, any differences relate to the information or instructions conveyed by the printed matter and not in any structure of the product. The product is known in the art, and a new intended use for the product does not constitute patentable subject matter. *In re Schreiber*, 128 F. 3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997). The following is considered printed matter: self care documentation, acknowledgement section, step-by-step instructions, recording device, record card, information device, contents map.

11. With respect to Claim 4: The claim does not set forth what quantity is associated with "one month of catheterizations", therefore it is the examiner's position that even one catheter can be a month's supply if the patient only needs it once a month.

12. With respect to Claim 20: See House, column 9, lines 5-67.

***Allowable Subject Matter***

13. Claims 5, 7, and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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14. Claims 15-19 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jamisue A. Webb whose telephone number is (703) 308-8579.

The examiner can normally be reached on M-F (7:30 - 4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703)308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jaw  
April 16, 2003

  
WEILUN LO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700